Examiner: D. Yabut

REMARKS

Claims 1, 11, 24, 30, and 40 have been amended. Claim 8 has been cancelled. Claims 4-7, 9, 22, 23, 27, and 29 were cancelled in a previous Response(s). Claims 1-3, 10-21, 24-26, 28, and 30-40 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendments to the Claims

No new matter has been added by the amendments to claims 1, 24, and 30 made herein. These amendments were made only to clarify the structure of the claimed implant. When the pointed end portion of the implant is moved through tissue, the pointed end portion is aligned with the body tissue at a location where the implant is to be moved into the body tissue. The pointed end portion has a maximum transverse length that is no greater than the maximum transverse length of the body portion, *i.e.* the pointed end portion is not wider than the body portion, thus facilitating accurate placement of the implant in body tissue. This concept is illustrated in any of Figures 1-9, 11, and 12. For example, note the transverse lengths of pointed end portion 24 and body portion 22 of the implant shown in Figure 1. *See* also paragraphs [0030] and [0049] of the published application, U.S. Patent Application Publication 2004/0010287 A1; hereinafter "published application."

No new matter has been added by the amendment to claim 11 made herein. This claim was amended only to provide proper antecedent basis for all terms recited therein.

No new matter has been added by the amendment to claim 40 made herein. This claim was amended only to correct an inadvertent typographical error.

Rejection under 35 U.S.C. §102(b)

Claims 1-3, 8, 10, 11, 18-20, 30, and 32-36 were rejected under 35 U.S.C. §102(b) as being anticipated by Adams (U.S. Patent No. 6,099,552; hereinafter "Adams"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Examiner: D. Yabut

<u>Adams</u>

First, Applicant notes that the Adams patent has been discussed extensively in several of the previously-filed Responses. These discussions are incorporated herein by reference.

Generally, Adams discloses compression devices (and methods for deploying and using the devices) useful to cause hemostasis of blood vessels located along the gastrointestinal tract in treatment of gastrointestinal bleeding such as that associated with peptic ulcer disease. *See* abstract and column 1, lines 4-7; 35-38. The device comprises a clip including a stem having a first end and a second end, the first end including an anchor and the second end including a bolster at or near the end of the stem. *See* abstract and column 1, lines 38-41. The stem may include at least one transverse hole therein. The bolster is slidable about the stem and includes a flap adapted for insertion into the transverse hole. When the device is deployed into a patient, the flap remains in the hole to apply pressure against the wall of the gastrointestinal tract. *See* column 1, lines 41-45; column 2, lines 2-3, 54-57; and Figure 1.

Instant Invention

The instant invention provides an implant for securing a suture relative to a body tissue (hard and/or soft) in a patient's body. The implant includes a body portion and a pointed end portion. The body portion is movable through an opening in the body tissue and has a longitudinal central axis and a maximum transverse length transverse to the longitudinal central axis. The body portion includes a first passage extending therethrough transverse to the longitudinal central axis (of the body portion). A suture may be threaded through this first passage. The pointed end portion is connected with the body portion along the longitudinal central axis and is operable for piercing the body tissue. The pointed end portion has a maximum transverse length transverse to the longitudinal central axis no greater than the maximum transverse length of the body portion. Thus, the implant has a pointed end portion that is no wider than the body portion and the pointed end portion. The second passage formed through both the body portion and the pointed end portion. A suture may be threaded through the second passage or through both the first and second passages. *See*, for example, paragraphs [0006]-

Examiner: D. Yabut

[0011]; [0013]; [0014]; [0022]; [0030]-[0034]; [0046]; and [0184]-[0190] and Figures 1, 2, and 11 of the published application.

Argument

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *See* MPEP 2131.

Applicant considers the Examiner's conclusion of anticipation of the claimed invention by Adams as an assertion (by the Examiner) that the compression clips described by Adams are equivalent to the claimed implant.

Applicant respectfully disagrees and submits that the Examiner's application of the teachings of Adams to the claimed implant is misguided at best.

The Examiner illustrates her interpretation of the structure of the compression device by labeling a partial reproduction of Figure 1 (of Adams) at page 3 of the current Office Action. The Examiner asserts that the structure of the claimed implant can be seen in the compression device of Adams as follows: the "body portion" extending along a central longitudinal axis from second end 103 (top) of stem 101 to a portion of the transverse hole 104 adjacent anchor 105; the "pointed end portion" extending along a central longitudinal axis from the portion of transverse hole 104 forming a part of the body and end portions through the anchor 105 to first end 102; and the transverse hole 104 adjacent anchor 105 is the "second passage" as it forms a part of both the body and end portions.

While Applicant does not necessarily disagree with the Examiner's interpretation of the structure of the compression device described by Adams, this interpretation does not represent the structure of the implant as currently claimed. The anchor 105 of Adams has flanges which extend at acute angles to the longitudinal central axis of stem 101 resulting with a device including a pointed end portion having a transverse length greater than the transverse length of the body portion. In contrast, the implant, as currently claimed, includes a pointed end portion having a maximum transverse length that is no greater than the maximum transverse length of

Examiner: D. Yabut

the body portion, *i.e.* the end portion is not wider than the body portion. This concept is clearly illustrated in any of Figures 1-9, 11, and 12.

The Examiner asserts that the transverse holes **104** in the stem **101** of the device described by Adams are operable for threading of sutures. Applicant respectfully disagrees. The Examiner has not presented any reasoning supporting this interpretation of the function of the holes **104**. The mere presence of holes in a device does not automatically render the holes operative for threading of sutures. According to Adams, holes **104** are provided to engage flaps **107** on a bolster **106** in order to lock the bolster **106** in position along stem **101**. *See* column 2, lines 43-45, 54-61; column 3, lines 5-14, and Figures 1 and 2. There is no teaching that holes **104** would allow for threading of a suture or even that sutures are necessary for or can improve the compression function of the device. Further, nowhere in Adams is it suggested that a suture, or anything akin to a suture, is used or can be used with the compression device. Thus, the Examiner, since she apparently bases her assertion on the assumption that holes **104** can function as the passages of the claimed implant solely on the presence of the holes **104**, is reading elements of the claimed invention into the prior art when the elements are not present.

Considering the above, the claimed implant is distinct from the compression device of Adams with regard to both structure and function. Therefore, the claimed implant is not an equivalent of the compression device of Adams and further, the claimed implant and device of Adams can not be used interchangeably.

Accordingly, Adams does not teach each and every element of the invention, as currently claimed, in independent claims 1 and 30, as is required to establish anticipation under 35 U.S.C. §102(b). Thus, independent claims 1 and 30 are not anticipated by Adams. As claims 2, 3, 10, 11, and 18-20 depend from claim 1 and claims 32-36 depend from claim 30, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over Adams for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

Examiner: D. Yabut

Rejections under 35 U.S.C. §103(a)

Claims 12-17, 21, and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams. Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz et al. (U.S. Patent 6,306,159 B1; hereinafter "Schwartz") and Hayhurst (U.S. Patent 4,741,330; hereinafter "Hayhurst"). Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz, Hayhurst, and Egan (U.S. Patent 6,106,545; hereinafter "Egan"). Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz, Hayhurst, and Huxel et al. (U.S. Patent 6,503,259 B2; hereinafter "Huxel"). Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Whittaker et al. (U.S. Patent 5,417,712; hereinafter "Whittaker"). Claims 37 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz. Claim 38 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz and Hayhurst. Claim 39 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz and Hayhurst. Claim 39 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Schwartz, Hayhurst, and Egan.

For reasons set forth below, Applicant respectfully submits that all of these rejections should be withdrawn.

It is noted that the references are described separately only in order to clarify what each reference teaches and not to argue the references separately.

The teachings of Adams are applied as above.

Schwartz

First, Applicant notes that the Schwartz patent has been discussed extensively in several of the previously-filed Responses. These discussions are incorporated herein by reference.

Generally, Schwartz discloses a device (and methods for deploying and using the device) for repairing a soft tissue defect, particularly a defect in the meniscus of the knee. *See* abstract and column 1, lines 9-15. The device includes an outer wall anchor and an inner menicscal anchor; the outer wall anchor for engaging against an outside wall of the meniscus on a first side

Examiner: D. Yabut

of a defect and the inner meniscal anchor for engaging an inner surface of the meniscus on a second side of a defect. The device also includes a suture which adjustably connects the anchors together. Tension on the suture pulls the anchors together to close the defect and a locking mechanism locks the suture in place. *See* abstract; column 1, lines 28-32; and column 4, lines 1-13. The outer wall anchor can be longitudinally shaped and have one or more holes through which sutures may pass freely. The inner anchor is shaped to resist movement once deployed and may be cannulated to allow for sliding of the suture. When the device is deployed, the suture loops through the holes in the outer anchor and both ends of the suture traverse back through the cannula of the inner anchor. When the suture is tensioned the outer wall flips into place to provide support for the outer wall. *See* column 1, lines 34-41.

Hayhurst

Hayhurst discloses a method and apparatus for anchoring and manipulating cartilage and other fibrous tissue within a joint during arthroscopic surgery. See abstract; column 1, lines 10-16; and column 2, lines 5-17. Generally, the apparatus includes a hollow tube, hollow needle, an anchoring device, and a suture. The hollow needle has open ends (tip and butt) and is associated with the hollow tube which is of equal or greater length than the needle. The tube fits movably within the needle. The anchoring device is deformed from its elongate shape within the tip of the hollow needle and the suture is attached thereto. In preparation for use, the free end of the suture is passed through the bore of the needle and the tube and extends through the butt of the needle. The anchoring device is then lodged into the tip of the needle by pulling on the suture. See abstract and column 2, lines 18-50. The needle is then used to pierce the cartilage and the tube is used to expel the anchoring device behind the cartilage to be anchored. The anchor then returns to its original shape. The needle and tube are then removed from the joint. The cartilage can then be secured, manipulated, and/or removed by application of tension to the suture. See abstract; column 2, line 56 to column 3, line 22; and Figure 1. Additionally, in one embodiment Hayhurst discloses permanent attachment of tissue with the suture/anchoring device. The exterior of this anchoring device has barb-like projections to anchor it in a hole drilled for that purpose. A retainer can be used to maintain tension in the suture and is slidable along the suture

Examiner: D. Yabut

in one direction and resists movement in the opposite direction to hold the tissue securely in place. *See* abstract; column 3, lines 23-35; column 8, lines 1-38; and Figures 10-14 and 17.

Egan

Egan discloses a suture tensioning and fixation device used for fastening of tissues. The device includes a suture thread and a suture retainer. The retainer has a first suture thread engaging a portion on the first end, a second suture thread engaging a portion opposite the first suture thread, and a third substantially centrally located suture thread. The retainer is adapted such that the segments of thread can be interwoven between the suture-engaging portions of the retainer and frictionally held. *See* abstract; column 1, lines 40-56; and Figure 1. The retainer and the suture thread can be bonded together under application of energy, such as thermal or ultrasonic energy, which melts the retainer material thus fixing the suture thread in place when cooled. *See* column 1, lines 57-67; column 2, lines 29-30; column 3, lines 19-45; and Figure 5.

Huxel

Huxel discloses a fastener and method for performing anastomosis (re-connection of severed ends of tubular organs). *See* column 1, lines 5-8. The apparatus is a fastener including a plurality of individual fastener pairs each having a piercing element with a pin that pierces the tissue to be repaired and a receiver portion that interlocks with the pin of the corresponding piercing element. A fastener dispenser is also disclosed that holds the piercing elements and receiver elements in juxtaposition and in a predetermined geometric configuration, such as a circle. In use, the tissues to be joined are positioned between the piercing elements and the receiving elements held in the dispenser. The dispenser then ejects the piercing elements and pushes them through the tissue and into the receiving elements causing the elements to interlock (piercing elements with the receiving elements) and capture the tissue there between. Since the fastener includes a plurality of individual fasteners, flexibility is maintained to allow for radial expansion of an organ such as that which occurs during peristalsis in the intestines. *See* abstract column 2, lines 1-27; and Figure 1.

Examiner: D. Yabut

Whittaker

Whittaker discloses an improved anchoring device for anchoring objects to bone. See abstract and column 1, lines 5-12. The device has a fastening means which permits the anchor to be fastened within a bone hole/tunnel while minimizing the stress on the body of the anchor during installation. See abstract and column 2, lines 52-60. The device includes a body, attachment for attaching the desired object to the body, and fastening means for fastening the anchor within a bone hole/tunnel. The body is divided into three portions; distal, middle, and proximate. The distal portion has a first end and a second end, the proximal portion also has a first end and a second end; and the middle portion extends from the second end of the distal portion to the first end of the proximal portion. The attachment may include a round or elongate hole extending diametrically through a portion of the body. The fastening means includes a curved central portion and multiple bone-engaging elements. Each of the bone-engaging elements is connected to the central portion and extends outwardly from the anchor body. See column 3, lines 17-44. The bone-engaging elements are cantilevered to the curved central portion such that during anchor insertion the stress generated by deformation of the fastening means is supported by the curved central portion. See column 8, lines 23-30. The device is capable of being deployed by any known anchor installation methods. See column 3, lines 5-7 and 45-47. The device can be made from polymeric or biodegradable materials and can be manufactured using both conventional polymer molding technology and metal-forming technology. See abstract; column 2, lines 48-51; and column 3, lines 1-4, 8-10.

Instant Invention

The instant invention is as applied above further including an implant assembly wherein the body portion is defined as "cylindrical" and the pointed end portion described as "more rigid than the body tissue." In addition to the implant, the assembly includes a suture connected to the cylindrical body under tension and extending through the first and second passages and a suture retainer. The retainer has a first configuration and a second configuration. In the first configuration it is freely slidable along the suture and in the second configuration it is secured

Examiner: D. Yabut

and connected to the suture maintaining the tension therein. *See* paragraphs [0030]; [0032]; and [0063]-[0074] and Figure 4 of the published application.

Argument

Applicant respectfully submits that the combination of the teachings of Adams with any or all of the teachings of the cited secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) does not obviate the invention as currently claimed.

Independent claims 1 and 30 recite, *inter alia*, an implant for securing a suture relative to a body tissue (hard and/or soft) in a patient's body. The implant includes a body portion and a pointed end portion. The body portion is movable through an opening in the body tissue and has a longitudinal central axis and a maximum transverse length transverse to the longitudinal central axis. The body portion includes a first passage extending there through transverse to the longitudinal central axis (of the body portion). A suture may be threaded through this first passage. The pointed end portion is connected with the body portion along the longitudinal central axis and is operable for piercing the body tissue. The pointed end portion has a maximum transverse length transverse to the longitudinal central axis no greater than the maximum transverse length of the body portion. Thus, the implant has a pointed end portion that is no wider than the body portion and the pointed end portion. The second passage formed through both the body portion and the pointed end portion. A suture may be threaded through the second passage or through both the first and second passages.

Independent claim 24 recites, *inter alia*, an implant assembly including an implant, a suture, and a retainer. The implant is similar to that which is recited in claims 1 and 30, with the exceptions of having a body portion defined as "cylindrical" and a pointed end portion described as "more rigid than the body tissue." In the claimed assembly the suture is connected to the cylindrical body under tension and extends through the first and second passages. The retainer has a first configuration and a second configuration; in the first configuration it is freely slidable along the suture and in the second configuration it is secured and connected to the suture maintaining the tension therein.

Examiner: D. Yabut

By rejecting these claims under 35 U.S.C. §103(a), the Examiner asserts that the claimed invention is merely an obvious combination of known elements.

Applicant respectfully disagrees and submits that all of the elements of the implant/implant assembly, as currently claimed, are <u>not</u> found in the prior art and further, even if all elements could be gleaned from the prior art, there is no motivation or suggestion to combine these elements.

First, with regard to claims 12-17, 21, and 26, all dependent on claim 1, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to use any of allogenic, autogenic, xenogenic, cortical bone, single piece of freeze dried bone, metal, metal alloy, biodegradable material, and/or bioerodible material in either soft tissue or bone with the device of Adams since it was known in the art that these materials are used with suture devices with soft tissue or bone.

Applicant respectfully disagrees. Regardless, as established above, Adams does not teach each and every element of the implant as currently claimed in claim 1. Thus, even if one were to use any of these materials with the device of Adams, one would not be using the claimed implant or implant assembly.

With regard to claims 24, 25, 28, and 37-40 rejected over Adams in view of Schwartz, inter alia, the Examiner asserts the following regarding the teachings of Schwartz: "Schwartz teaches a suture 40 being passed through and extending through first 24 and second 26 passages and being threaded through said first passage and said second passage, wherein the suture is operative to rotate an anchor 20 when under tension, and a retainer connected to the suture for maintaining tension in the suture (Figures 4-7; abstract; column 2, lines 14-16)."

Applicant respectfully submits that the Examiner's analysis of Schwartz is incomplete. While Schwartz discloses several different embodiments for securing the sutures (column 5, lines 1-2 and Figures 6-13), a retainer for maintaining tension on the sutures is not mentioned.

With regard to claims 24, 25, 28, 38, and 39 rejected over Adams in view of Schwartz and further in view of Hayhurst, *inter alia*, the Examiner asserts the following regarding the teachings of Hayhurst:

Examiner: D. Yabut

"Hayhurst teaches a retainer **68** having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture (see abstract, Figures 13-14, column 8, lines 25-32)."

Applicant respectfully disagrees with the Examiner's interpretation. The retainer disclosed by Hayhurst is movable along the suture in one direction only. *See* abstract and column 3, lines 28-31.

With regard to claims 25 and 39 rejected over Adams in view of Schwartz, Hayhurst, and Egan the Examiner asserts the following regarding the teachings of Egan:

"Egan teaches a retainer 24 connected to a suture 22 that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place (column 3, lines 5-30)."

Applicant does not disagree that Egan teaches bonding a retainer and a suture together with application of ultrasonic vibratory energy, however Egan does not remedy the deficiencies of Adam, Schwartz, and Hayhurst as he does not provide or suggest the missing elements such that his disclosure (Egan) can be combined (with Adams, Schwartz, and Hayhurst) to result with the implant assembly as currently claimed. Thus, even if one were to use ultrasonic vibratory energy with a device derived from a combination of the teachings of Adams, Schwartz, and Hayhurst, one would not be using the claimed implant assembly.

With regard to claim 28 rejected over Adams in view of Schwartz, Hayhurst, and Huxel the Examiner asserts the following regarding the teachings of Huxel:

"Huxel teaches a force distribution member 16 being disposed between a retainer and body tissue (Figure 8)."

Applicant respectfully disagrees. Gasket 16 is interposed between elements 12 and 14 (piercing and receiving elements) of the fastener array 10. See column 2, lines 60-67 and Figures 1 and 8. Thus, contrary to the Examiner's assertion, element 16 is not disposed between a retainer and body tissue.

With regard to claim 31 rejected over Adams in view of Whittaker the Examiner asserts the following regarding the teachings of Whittaker:

Examiner: D. Yabut

"Whittaker teaches that a suture passage may extend at an acute angle to the longitudinal axis, such as in Figures 13 and 16....Whittaker also teaches that having the passage ("central portion") at an angle may facilitate deformation of a suture 12 (column 8, lines 28-30)."

Applicant respectfully disagrees. The suture passages disclosed by Whittaker are designated as element **33** and each extends longitudinally along the outer surface of the body **6** of anchor **3**. Thus, contrary to the Examiner's assertion, the suture passages do not extend at acute angles to the longitudinal axis, but rather are parallel to this axis. Bone-engaging means **45** are shown as extending at an acute angle to the longitudinal axis. Furthermore, central portion **42** is a part of the bone-engaging means and not a suture passage. *See* column 6, lines 49-62; column 8, lines 1-33; and Figures 1 and 13.

Accordingly, based upon the above, it is clear that all of the elements of the claimed implant/implant assembly can not be found in the combination of the teachings of Adams with the teachings of any or all of the cited secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker).

Furthermore, even if one of ordinary skill in the art were to interpret the combination of the teachings of Adams with any or all of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker as disclosing all of the elements of the invention as claimed, the fact that each reference discloses a part of the invention such that all references together disclose all parts of the claimed invention does not, in and of itself, render the invention an obvious combination of the references.

"The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made." <u>In re Lamberti</u>, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

In addition to what is suggested by the combination of references, an Examiner must provide clear articulation of the reasons for his/her finding of obviousness. *See* MPEP 2142.

"Rejections based on obviousness cannot be sustained by mere conclusory statements, instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP 2141 III; KSR International Co. v. Teleflex, Inc. 550 US 398 (2007); 82 USPQ2d 1396.

Examiner: D. Yabut

Why would one of ordinary skill in the art be motivated to combine the teachings of Adams with any or all of the teachings of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker? The Examiner provides only vague generalizations in support of motivation and/or suggestion to combine the references such as "it is known in the art" and "to promote healing." The mere fact that something is known does not automatically give one reason to apply the knowledge. And the "promotion of healing" can be a goal of any surgical technique. Are there specific suggestions in the references to combine? What suggestion is made in the references that the combination of teachings would promote healing? Do the secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) suggest improvements for a device such as that disclosed by Adams? Without answers to these questions, the Examiner's statements regarding obviousness are merely unsupported conclusions and thus, insufficient to support a *prima facie* case of obviousness.

Based on both the above discussion of the teachings of the cited references and the above discussion of motivation/suggestion, Applicant respectfully submits that the combined patents (Adams with Schwartz, Hayhurst, Egan, Huxel, and Whittaker) do not teach all of the elements of the invention as currently claimed and thus, they (the combined patents) can not possibly suggest that their combination produces the claimed implant/implant assembly. Thus, motivation to combine is non-existent.

Regarding Whittaker, the Examiner concludes "It would have been obvious to one of ordinary skill in the art at the time of invention to modify Adams by having one of the passages being formed in the body portion and in the pointed end portion, as taught by Whittaker, since Applicant has not disclosed that having the passage being formed in both the body portion and in the pointed end portion solves any stated problem or is for any particular purpose and it appears that the device of Adams would perform equally well." Emphasis added herein by Applicant.

Formation of a passage through at least a portion of the tip allows the implant to be rotated earlier in the insertion process than fasteners with more distally placed passages. Additionally, the proximate passage provides better leverage and control of the insertion and rotation

Examiner: D. Yabut

processes. Applicant respectfully points out to the Examiner that this concept was discussed in at least three of the previously-filed Responses: at page 10 of the Response filed on December 22, 2008; at pages 9-10 of the Response filed on May 15, 2008; and at pages 9-10 of the Response filed on October 30, 2007.

Furthermore, Applicant respectfully submits that there is no reasonable basis for the Examiner's conclusion as Whittaker teaches passages only in the body portion of the anchor (element 33 in Figure 1) and rotation is counter to the purpose of Adams considering that the stem (as disclosed by Adams) must remain in the original orientation within the tissue such that the bolsters can be inserted.

Based upon all of the above arguments, it is clear that neither the cited patents (Adams with Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) nor any other prior art teach or suggest an implant or an implant assembly as currently claimed.

Accordingly, Applicant submits that independent claims 1, 24, and 30 are patentable over Adams in view of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker. As claims 2, 3, 10-21, and 26 depend from claim 1; claims 25 and 28 depend from claim 24; and claims 31-40 depend from claim 30, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that these dependent claims are allowable over Adams in view of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker at least for the same reasons.

In light of all of the foregoing arguments, Applicant respectfully requests reconsideration and withdrawal of all rejections of claims under 35 U.S.C. §103(a).

Examiner: D. Yabut

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition

for allowance and early passage of this case to issue is respectfully requested. If any questions

remain regarding this amendment or the application in general, a telephone call to the

undersigned would be appreciated since this should expedite the prosecution of the application

for all concerned. The fee for a two month extension of time pursuant to Section 1.17(a)(2) in

the amount of \$245 and the fee for a request for continued examination pursuant to Section 1.17(e)

in the amount of \$405 are believed to be due and are being paid via credit card. No other fees are

believed to be due at this time. However, please charge any other required fee (or credit

overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No.

782-A03-003-1).

Respectfully submitted,

/Paul D. Bianco/

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771

FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.

21355 East Dixie Highway, Suite 115

Miami, Florida 33180

Tel: 305-830-2600; Fax: 305-830-2605

e-mail: pbianco@fggbb.com

22